directional hooks. Alternatively, the guide wire may be capable of cross-locking itself once the guide wire is advanced to the selected section of the disc.

Still according to this embodiment, the proximal portion of the guide wire may preferably have an outer diameter between about 0.005-0.025 inches. The distal portion of the guide wire may preferably have an outer diameter between about 0.002-0.012 inches. The proximal portion of the guide wire may preferably be between about 10-15 inches long. The distal portion of the guide wire may preferably be between about 0.2-1.2 inches long. The distal portion of the guide wire may preferably have a length at least one-half of a diameter of the nucleus pulposus.

Please replace the paragraph beginning on page 7, line 14, with the following rewritten paragraph:

The catheter of the apparatus may further include a functional element for performing a function adjacent the selected section, such as delivering energy, adding material and removing material. In one aspect, the functional element may also be an irrigation lumen extending from a proximal end of the catheter to the intradiscal section. In another aspect, the functional element may comprise a thermal energy delivery device. A thermal energy source may be operably attached to the thermal energy delivery device through the catheter. Examples of the thermal energy delivery devices include, but are not limited to, microwave probes, optical fibers, radio frequency electrodes, thermal resistive heaters, integrated circuits and ultrasound emitters.

Please replace the paragraph beginning on page 8, line 17, with the following rewritten paragraph:

According to this embodiment, causing the guide wire to navigate itself may include applying a longitudinal force to the guide wire which is sufficient to advance the guide wire through the nucleus pulposus and around the inner wall of an annulus fibrosus, but which force is insufficient for the guide wire to puncture the annulus fibrosus.

Please replace the paragraphs beginning on page 8, line 25, with the following rewritten paragraphs:

Still according to this embodiment, the method may further include performing a function adjacent the selected section by using a catheter that includes a functional element for performing the function. The function may be delivering energy, adding material and removing material. For example, the functional element may be a heating element coupled with a temperature sensor. Such a heating element may be a coil heating element, a flat heating element, or a flex ribbon heating element. Alternatively, the guide wire itself may include a heating element.

B4

The method according to the present invention may further include using the function to treat annular fissures, for example, by adding sufficient energy to the selected section of the disc. The sufficient energy may be added to shrink the collagen component of the annulus fibrosus around the fissure or to cauterize granulation tissue in the fissure.

Alternatively, the functional element may be a lumen capable of delivering or aspirating material. Accordingly, the method may further include placing a material in the disc. Such a material may be electrolyte solutions, contrast media, pharmaceutical agents, chemonucleolytic enzymes, hydrogel, osteoinductive substances, chondrocyte-inductive substances, sealants, collagen, fibrinogen and thrombin, and any combination thereof.

Please replace the paragraph beginning on page 12, line 6, with the following rewritten paragraphs:

~~FIG. 9A~~ is a cross-sectional view of a specific embodiment of the distal tip of the guide wire according to the present invention with a hook locking tip.

B5

Please replace the paragraphs beginning on page 13, line 13, with the following rewritten paragraphs:

According to this embodiment, the guide wire is built to possess (a) sufficient rigidity to be advanceable through a nucleus pulposus and through and/or around the inner wall of an annulus fibrosus under a force applied longitudinally to the proximal end of the core wire, (b) insufficient penetration ability to be advanceable out through the annulus fibrosus under the applied force, and (c) sufficient flexibility in a direction of a disc plane to be compliant with the inner wall.

B6

Also according to this embodiment, the distal portion of the guide wire includes a spring coil to adjust flexibility of the guide wire. A forming ribbon may be incorporated in the distal portion of the guide wire to support the spring coil. The spring coil may be fully coated with Teflon or other biocompatible materials. The distal portion of the guide wire may be tapered to a smaller diameter toward the distal end.

Still according to this embodiment, the distal portion of the guide wire has a distal tip at the extremity of the distal portion of the guide wire. The distal portion of the guide wire may have one or more flat sides. The distal tip may be configured to be non-piercing through an annulus fibrosus, for example, including a blunt tip or a rolling ball tip. The distal tip may also include a locking mechanism for securing the guide wire within the selected section of the intervertebral disc, such as within an intradiscal section of the disc adjacent an inner wall of an annulus of the disc. The locking mechanism may include a retractable hook or a plurality of directional hooks. Alternatively, the guide wire may be capable of cross-locking itself once the guide wire is advanced to the selected section of the disc.

Please replace the paragraph beginning on page 14, line 24, with the following rewritten paragraph:

The catheter of the apparatus may further include a functional element for performing a function adjacent the selected section, such as delivering energy, adding material and removing material. In one aspect, the functional element may also be an irrigation lumen extending from a proximal end of the catheter to the intradiscal section. In another aspect, the functional element may comprise a thermal energy delivery device. A thermal energy source may be operably attached to the thermal energy delivery device through the catheter. Examples of the thermal energy delivery devices include, but are not limited to, microwave probes, optical fibers, radio frequency electrodes, plasma and/or ion generators, and ultrasound emitters.

Please replace the paragraph beginning on page 16, line 1, with the following rewritten paragraph:

The operational portions of the apparatus of the present invention are guided to a location in or near the annular fissure in the annulus of the intervertebral disc using techniques and

apparatuses typical of percutaneous interventions. For convenience and to indicate that the apparatus of the invention can be used with any insertional apparatus that provides access and proximity to the intervertebral disc, including many such insertional apparatuses known in the art, the term "introducer" is used to describe this aid to the apparatus and method. An introducer has an internal introducer lumen with a distal opening at a terminus of the introducer to allow insertion and subsequent manipulation of the operational portions of the apparatus through the body into and within the interior of a disc.

Please replace the paragraph beginning on page 16, line 21, with the following rewritten paragraph:

According to this embodiment, causing the guide wire to navigate itself may include applying a longitudinal force to the guide wire which is sufficient to advance the guide wire through the nucleus pulposus and through and/or around the inner wall of an annulus fibrosus, but which force is insufficient for the guide wire to puncture the annulus fibrosus.

Please replace the paragraphs beginning on page 16, line 29, with the following rewritten paragraphs:

Still according to this embodiment, the method may further include performing a function adjacent the selected section by using a catheter that includes a functional element for performing the function. The function may be delivering energy, adding material and removing material. For example, the functional element may be a heating element coupled with a temperature sensor. Such a heating element may be a coil heating element, a flat heating element, or a flex ribbon heating element. Alternatively, the guide wire itself may include a heating element.

The method according to the present invention may further include using the function to treat an annular fissure, for example, by adding sufficient energy to the selected section of the disc. The sufficient energy may be added to shrink the collagen component of the annulus fibrosus around the fissure or to cauterize granulation tissue in the fissure and thus, stimulate a healing response by the body.

Alternatively, the functional element may be a lumen capable of delivering aspirating material. Accordingly, the method may further include placing a material in the disc. Such a material may be electrolyte solutions, contrast media, pharmaceutical agents, chemonucleolytic enzymes, hydrogel, osteoinductive substances, chondrocyte-inductive substances, sealants, collagen, fibrinogen and thrombin, and any combination thereof.

Please replace the paragraph beginning on page 18, line 7, with the following rewritten paragraph:

A treatment catheter with a lumen for at least the guide wire is positioned over the guide wire and slid over the guide wire and navigated to the distalmost portion of the guide wire within the disc. The treatment catheter is configured to provide a function selected from ablation or shrinkage, delivery of medicaments, suction, viewing or monitoring within the disc, ultrasound delivery for treatment, mechanical manipulation, and/or ionization of disc tissue.

Please replace the paragraph beginning on page 18, line 22, with the following rewritten paragraph:

The following descriptions of **Figures 1** to **12** describe specific embodiments of the invention. The guide wire and treatment catheter of the present invention is illustrated but is not limited to this embodiment. The descriptive language used both in the specification and claims is for the purposes of clarity and convenience and not with any purpose or implied limitation to the surgical art or along a columnar vertebral structure as is typical in the spinal column.

Please replace the paragraphs beginning on page 19, line 16, with the following rewritten paragraphs:

**FIG. 2** illustrates that the mechanical characteristics of flexible distal section 30 of guide wire 10 are selected to have (1) sufficient column strength along the longitudinal axis of the guide wire to be able to advance and push through the nucleus pulposus 120 and (2) different flexural strengths along two axes orthogonal to the longitudinal axis to allow controlled bending of the guide wire 10. These parameters make the guide wire easily conformable and guidable along or directly through inner wall 22 of the annulus fibrosus 122 to reach a desired location,

such as the posterior wall along posterior medial annulus 138. Distal tip 20 of the guide wire 10 is preferably anti-traumatic such that the guide wire does not penetrate through the fissures or tears 44 in the annulus.

Guide wire 310 is illustrated in one embodiment in **FIG. 3**. The guide wire 310 consists of a core with a generally constant diameter from a proximal portion to a distal tip 320. A flexible distal portion 330 is located at or near the distal tip 320 of guide wire 310. A coil 315 is positioned at or near the distal tip such that a differential flexibility characteristic allows the guide wire to navigate through the nucleus pulposus of the disc.

B13 cont.

Referring to **FIG. 4A**, the guide wire 410 is configured with a tapering section 411 which provides a differential bending stiffness through the distal portion 425 of the guide wire. Flexible distal portion 430 includes a coil 415 which allows the tapering section 415 to curve and to navigate along the wall of the annulus. Blunt distal tip 420 limits and prevents the distal tip from penetrating large fissures in the annulus fibrosus.

In **FIG. 4B**, the catheter 400 is shown with a lumen 401 which is large enough to pass over the guide wire 410. The catheter 400 is sized to pass over the distal portion 425 and flexible distal portion 430 and distal tip 420. It is preferable that the catheter 400 have a larger diameter than the entire core guide wire 410 such that the distal end of the catheter may extend beyond the placement of the distal end 420 of guide wire 410.

Please replace the paragraphs beginning on page 20, line 23, with the following rewritten paragraphs:

Referring now to **FIG. 5A**, the intervertebral disc is illustrated with a posterior aspect 103 and an anterior aspect 102. The introducer 540 is inserted through the body into the nucleus pulposus 120 of the disc. The introducer needle has a hub 545 which is located outside of the patient's body to receive and guide the core wire. The introducer is preferably not inserted into the annulus fibrosus 122 but can be positioned either away from the fissures or tear 44 or on the same posterior aspect (not shown).

B14

**FIG. 5B** demonstrates the guide wire 510 inserted through the hub 545 and introducer 540 through the body to the nucleus pulposus 120. The guide wire 510 has sufficient rigidity and torsional characteristics such that the guide wire is advanced through the introducer 540 and

navigates along or through the inner wall of the annulus fibrosus. The distal portion 530 of the guide wire is then positioned along the annular fissure or tear before treatment.

Please replace the paragraph beginning on page 21, line 19, with the following rewritten paragraph:

In **FIG. 5E**, the catheter 500 is inserted into the disc through sheath 550. Catheter 500 has a distal portion 531 which is configured to a desired treatment modality and function such as ablation of nucleus pulposus material by the delivery of energy, shrinkage or associated collagen structures near the annular fissure or tear 44 by delivery of energy, suction of extraneous herniated material, delivery of medicaments for the relief of pain associated with a fissure or herniation, insertion of a balloon catheter for expansion of the nuclear material, ultrasound monitoring, visual monitoring of the nucleus or annulus via fiber optic or diagnostic delivery of fluoroscopic solutions. In a preferred embodiment, the catheter 500 includes a heating element at or near the distal portion 531 such that the annular fissure may be treated with thermal energy such that the fissure is sealed. It will be appreciated that the guide wire 510 may remain in place and catheter 500 may be "exchanged" such that different functional catheters as described above may be inserted and withdrawn to perform a specific function or a variety of separate functions. This is advantageous in that the traumatic effect of a percutaneous surgical procedure is limited in that a single surgical site may provide various treatments without the need for multiple surgical sites.

Please replace the paragraphs beginning on page 23, line 24, with the following rewritten paragraphs:

Referring to **FIG. 6A**, a specific embodiment of the core guide wire 610 with a distal hooking tip 635 is illustrated to fix the modular guide wire to the interior annulus wall after final position is achieved. Thus, displacement of the guide wire is prevented during subsequent exchange and withdrawal of other system components. The guide wire 610 is inserted through the introducer (not shown) and navigated to a desired portion along the inner wall of the annulus. Distal locking tip 635 is inserted and held in place such that the distal portion 630 remains in place. The catheter 600 slides through sheath 650 into the nucleus 120 of the intervertebral disc.

The distal portion 631 of catheter 600 is positioned at the annular fissure 44 for performing a function as described above. **FIG. 6B** illustrates the catheter 700 placed within the intervertebral disc with sheath 650 removed.

In another specific embodiment, the guide wire has a cross-locking configuration to fix the modular guide wire to the interior annulus wall. **FIG. 7A** illustrates a guide wire 710 passing through an introducer sheath 750 and being navigated along the annulus wall and locked into place with distal locking tip 735. Flexible distal portion 730 is crossed-over the guide wire 710 and locked into an anterior portion of the disc. The catheter 700 is slid over the guide wire 710 to place distal portion 731 within the nucleus pulposus along annular fissure 44. **FIG. 7B** illustrates the catheter 700 in place without the sheath 750.

Please replace the paragraph beginning on page 24, line 20, with the following rewritten paragraph:

In a detail figure, **FIG. 8B** illustrates the catheter 800 in cross-section according to the present invention over a section of the guide wire 810. The distal tip 821 of heating catheter 800 has an opening into the lumen 801 for passing over the guide wire 810. The internal lumen near the distal portion 831 contains a heating coil 860 for resistive heating. The heating coil 860 is electrically connected to an electrosurgical generator at the proximal portion of the catheter (not shown). A thermal sensor 870 such as a thermocouple is also positioned at the distal portion 831 of the catheter 800. A potting material can be used to fix the position of the thermal sensor 870 and provide a larger area from which to measure the temperature within the area. The thermal sensor 870 is connected by conductor 872 to a sensor located preferably within the electrosurgical generator but alternately within a separate unit. The sensor is of conventional design, including but not limited to a thermistor, T type thermocouple with copper constantan junction, J type, E type, and K type thermocouples, fiber optics, resistive wires, infrared detectors, integrated circuits and the like. Optionally, there may be a separate lumen for the thermal sensor connection.

Please replace the paragraph beginning on page 25, line 27, with the following rewritten paragraph:

In **FIG. 11**, the shaped memory characteristics of the guide wire are illustrated. The guide wire 1110 is substantially straight along a proximal portion of the core wire. The distal portion 1130 is pre-shaped into a curve shaped such that the distal tip 1120 will curve toward the guide wire after deployment such as in the cross-locking embodiment describe above in **FIG. 7A**. It will be appreciated that any pre-shaped configuration may be used to define the distal portion of the guide wire.

Please replace the paragraph beginning on page 27, line 1, with the ~~following~~ rewritten paragraph:

**FIG. 12B** illustrates a heating element 1261 which is a flat element. The flat elements may be etched onto a surface of the catheter or separate element to be bonded to the catheter by chemical etching, electrochemical etching, photo etching or physical etching. Additionally, the flat heating elements 1261 may be chemically, electrically or physically deposited onto the surface. Similarly, in **FIG. 12C**, the heating element may be in the form of a flex ribbon heating element 1262. Each heating element 1261 may be individually connected to the electrosurgical generator to deliver power and energy either in parallel or series such that the energy is delivered between each element and through the tissue.

Please replace the paragraphs beginning on page 27, line 16, with the following rewritten paragraphs:

Additionally, a radiographically opaque marking device can be included in the distal portion of the catheter (such as in the tip or at spaced locations throughout the intradiscal portion) so that advancement and positioning of the intradiscal section can be directly observed by radiographic imaging. Such radiographically opaque markings are preferred when the intradiscal section is not clearly visible by radiographic imaging, such as when the majority of the catheter is made of plastic instead of metal. A radiographically opaque marking can be any of the known (or newly discovered) materials or devices with significant opacity. Examples include but are not limited to a steel mandrel sufficiently thick to be visible on fluoroscopy, a tantalum/polyurethane tip, a gold-plated tip, bands of platinum, stainless steel or gold, soldered spots of gold and polymeric materials with radiographically opaque filler such as barium sulfate.

A resistive heating element or a RF electrode(s) may provide sufficient radio-opacity in some embodiments to serve as a marking device.

In a specific embodiment, temperatures delivered through the heating element may be detected at sensors to provide feedback for maintaining a selected power in the electrosurgical generator. The actual temperatures are measured at a temperature measurement device, and the temperatures are displayed at a user interface and display. A control signal is generated by a controller that is related to the actually measured temperature and a desired temperature. The control signal is used by power circuits to adjust the power output in an appropriate amount in order to maintain the desired temperature delivered at the respective sensor. A multiplexer can be included to measure current, voltage, and temperature at the sensors so that appropriate energy can be delivered to resistive heating elements.

B20 CONT'

It will also be appreciated by one skilled in the art that the core of the guide wire can also provide the function of differential flexibility by varying the thickness in one or more dimensions (for example, the "thin" dimension, the "thick" dimension, or both) along the length of the guide wire. A guide wire that tapers (becomes gradually thinner) toward the distal tip of the guide wire will be more flexible and easier to bend at the tip than it is at other locations along the guide wire. A guide wire that has a thicker or more rounded tip than more proximal portions of the mandrel will resist bending at the tip but aid bending at more proximal locations. Thickening (or thinning) can also occur in other locations along the guide wire. Control of the direction of bending can be accomplished by making the guide wire more round, i.e., closer to having 1:1 diameter ratios; flatter in different sections of the guide wire; or by varying the absolute dimensions (increasing or decreasing the diameter). Such control over flexibility allows instruments within a catheter over the guide wire to be designed that minimize bending in some desired locations (such as the location of connector of an electrical element to avoid disruption of the connection) while encouraging bending in other locations (e.g., between sensitive functional elements). In this manner, a guide wire that is uniformly flexible along its entire length, is variably flexible along its entire length, or has alternating more flexible and less flexible segment(s), is readily obtained simply by manufacturing the guide wire with appropriate thickness at different distances and in different orientations along the length of the guide wire.